REMARKS

Reconsideration is respectfully requested. Applicants have deleted the word "optionally" in claim 1. Furthermore, claims 3 and 17 have been amended to more particularly point out and distinctly claim the subject matter which Applicants regard as their invention. After entry of the present amendments, claims 1-18 and claims 33-34 will be pending.

Rejection Under 35 U.S.C. § 102(e)

Claims 1, 3-6, 9, 11, 15, 17, 18, and 33 are rejected under 35 U.S.C. § 102(e) as being anticipated by Kamiya et al. The Office Action states:

> "Kamiya et al. teach a patch comprised of two water soluble layers (abstract). Antiseptics are specified (column 8 line 13). Gelatin and polyacrylic acid are specified in one layer and polyvinyl alcohol in the second layer (Table 1). Propylene glycol is specified (column 5, line 11). Water is disclosed (column 4 lines 60-67)."

First of all, Applicants submit that the claimed invention was made prior to Kamiya's patch. Attached thereto is a declaration under C.F.R. § 1.131 which shows that the instant invention was completed prior to June 27, 1996, the filing date of the Kamiya et al. reference. Specifically, the declaration shows that a film having a bioadhesive layer made of hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose, and a non-adhesive backing layer made of hydroxyethyl cellulose was formed on June 4, 1996.

In addition to the claimed invention being made prior to the date of Kamiya's patch, Applicants also request the Examiner to review and reconsider the argument made in the previous Response. That is, that Kamiya et al. only teach a patch that is placed on the surface of skin before taking a bath. The cited reference does not teach or suggest the use of the patch on a surface such as the mucosa, which is not only inherently wet, but is also lubricated. Furthermore, the patch listed in Table 1 which comprises gelatin and polyacrylic acid, is applied to the shoulder (see 13:8-10). Although gelatin and polyacrylic acid may be used in the first layer of

the instant invention, again, it cannot be assumed that these same materials in the Kamiya patch would also cause it to stick to the mucosa.

The instant invention, however, is "placed in contact with a mucosal surface" or "adheres to mucosal surfaces", as required by independent claims 1 and 17 and those dependent thereon. A skin surface cannot be considered equivalent to a mucosal surface., and therefore, each and every element of the claims are not met by Kamiya et al.

Thus, not only is the claimed invention not anticipated by the patch of Kamiya et al., but the instant invention was made prior to the invention of the Kamiya et al. patch. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-7, 9-15, 17, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Inaba et al. The Office Action states:

> "Inaba et al. teach a three layer composition comprising an outer control release layer comprising polyvinyl pyrrolidone and hydroxy alkyl cellulose (Figure 1 and Claim 1A). A drug storing layer comprising hydroxypropyl cellulose is disclosed (Claim 8). Glycerin is specified (Claim 1C). Prostaglandins, known for lowering blood pressure, are disclosed (column 1 line 48).
>
> Vinyl acetate is specified (Claim 1B). As to the claimed adhesive layer, this property must be inherent in the Inaba et al. composition because it possesses the same polymer as that claimed as an adhesive, namely, polyvinyl pyrrolidone."

Applicants respectfully traverse this rejection and once again request that the Examiner reconsider the argument set forth in the previous Response. That is, that Inaba et al. only teach a layered film that has three layers (two drug release controlling layers and one drug storing layer). Inaba et al. do not suggest the use of two layers.

Furthermore, Inaba et al. teach a drug release controlling layer that comprises one or more water-insoluble polymers. The instant invention comprises only water-erodable polymers.

Thus, Applicant's claimed film and that of Inaba et al. are clearly different. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Objection to the Disclosure

The Office Action states:

> "The disclosure is objected to because of the following informalities: On page 7 line 28, page 16 lines 23, 27, page 17 lines 4, 9, 12, 14, 16, 21 and page 19 line 3 "ETC" is nonlimiting. "And the like" is suggested."

Applicants have made the appropriate changes to the disclosure as recommended by the Examiner. Accordingly, withdrawal of the objection is respectfully requested.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-16 have been rejected by the Examiner under 35 U.S.C. § 112, first paragraph. The Office Action states:

> "...the specification, while being enabling for a film containing a drug, does not reasonably provide enablement for a film not containing a drug. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make the invention commensurate in scope with these claims. Page 6 lines 6-28 specify a film containing a drug.
>
> Thus, "optionally" in claim 1 impermissibly broadens the scope of the claim."

Applicants have amended claim 1 to no longer recite that the device "optionally" incorporates a drug. Thus, after entry of the present amendment, Applicants respectfully request withdrawal of the rejection.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 3, 17-18 have been rejected by the Examiner under 35 U.S.C. § 112, second paragraph. The Office Action states:

> "In claim 17 lines 6, 7 "said first erodible" has no antecedent in the preamble. In line 2 is "A" intended before pharmaceutical?
>
> In claim 3 lines 2, 7 "selected from" is indefinite. Is 'the group consisting of' intended after the phrase? If so, "or" in lines 6, 8 is indefinite. A Markush group with "selected from" language should be a list of elements, the last preceded by "and".
>
> In lines 5, 6 "Derivatives" is vague; which ones?"

Applicants have amended the claims to place them in conformity with 35 U.S.C. § 112, first paragraph. Thus, after entry of the present amendment, Applicants respectfully request withdrawal of the rejection.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 359872000821. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: 11/19, 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

1. Paragraph 6 at the bottom of page 7.

As used herein, the term "water-erodable" means that the component, device, layer, etc. erodes in water-based media such as saliva, over time. Such erosion in water may be due to factors such as dissolution, dispersion, friction, gravity, [etc.] and the like.

2. Paragraph 3 on page 16.

Examples of anti-inflammatory analgesic agents include acetaminophen, methyl salicylate, monoglycol salicylate, aspirin, mefenamic acid, flufenamic acid, indomethacin, diclofenac, alclofenac, diclofenac sodium, ibuprofen, ketoprofen, naproxen, pranoprofen, fenoprofen, sulindac, fenclofenac, clidanac, flurbiprofen, fentiazac, bufexamac, piroxicam, phenylbutazone, oxyphenbutazone, clofezone, pentazocine, mepirizole, tiaramide hydrochloride, [etc.] and the like. Examples of steroidal anti-inflammatory agents include hydrocortisone, predonisolone, dexamethasone, triamcinolone acetonide, fluocinolone acetonide, hydrocortisone acetate, predonisolone acetate, methylpredonisolone, dexamethasone acetate, betamethasone, betamethasone valerate, flumetasone, fluorometholone, beclomethasone diproprionate, fluocinonide, [etc.] and the like.

3. Paragraphs 1, 2, and 3 respectively on page 17.

Examples of antihistamines include diphenhydramine hydrochloride, diphenhydramine salicylate, diphenhydramine, chlorpheniramine hydrochloride, chlorpheniramine maleate isothipendyl hydrochloride, tripelennamine hydrochloride, promethazine hydrochloride, methdilazine hydrochloride, [etc.] and the like. Examples of local anesthetics include dibucaine hydrochloride, dibucaine, lidocaine hydrochloride, lidocaine, benzocaine, p-buthylaminobenzoic acid 2-(die-ethylamino) ethyl ester hydrochloride, procaine hydrochloride, tetracaine, tetracaine

hydrochloride, chloroprocaine hydrochloride, oxyprocaine hydrochloride, mepivacaine, cocaine hydrochloride, piperocaine hydrochloride, dyclonine, dyclonine hydrochloride, [etc.] and the like.

Examples of bactericides and disinfectants include thimerosal, phenol, thymol, benzalkonium chloride, benzethonium chloride, chlorhexidine, povidone iode, cetylpyridinium chloride, eugenol, trimethylammonium bromide, [etc.] and the like. Examples of vasoconstrictors include naphazoline nitrate, tetrahydrozoline hydrochloride, oxymetazoline hydrochloride, phenylephrine hydrochloride, tramazoline hydrochloride, [etc.] and the like. Examples of hemostatics include thrombin, phytonadione, protamine sulfate, aminocaproic; acid, tranexamic acid, carbazochrome, carbaxochrome sodium sulfanate, rutin, hesperidin, [etc.] and the like.

Examples of chemotherapeutic drugs include sulfamine, sulfathiazole, sulfadiazine, homosulfamine, sulfisoxazole, sulfisomidine, sulfamethizole, nitrofurazone, [etc.] and the like. Examples of antibiotics include penicillin, meticillin, oxacillin, cefalotin, cefalordin, erythromcycin, lincomycin, tetracycline, chlortetracycline, oxytetracycline, metacycline, chloramphenicol, kanamycin, streptomycin, gentamicin, bacitracin, cycloserine, [etc.] and the like.

4. Paragraph 1 on page 19.

disodium EDTA, sodium citrate and sodium laurylsulfate, azone, sodium cholate, sodium 5-methoxysalicylate, sorbitan laurate, glyceryl monolaurate, octoxynonyl-9, laureth-9, polysorbates, [etc.] and the like.

In the Claims:

1. (Twice Amended) A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface, a second, water-erodable non-adhesive backing layer, and [optionally] a pharmaceutical incorporated with said first layer, said second layer, or both layers, wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer.

3. (Amended) The pharmaceutical carrier device of claim 1, wherein said first water-erodable adhesive layer comprises a film forming polymer selected from the group consisting of hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl methyl cellulose, polyvinyl alcohol, polyethylene glycol, polyethylene oxide, ethylene oxide-propylene oxide co-polymers, collagen [and derivatives], gelatin, albumin, polyaminoacids [and derivatives], polyphosphazenes, polysaccharides [and derivatives], [or] chitin, and chitosan, alone or in combination, and a bioadhesive polymer selected from the group consisting of polyacrylic acid, polyvinyl pyrrolidone, and [or] sodium carboxymethyl cellulose, alone or in combination.

17. (Twice Amended) A layered flexible film disk which adheres to mucosal surfaces for the localized delivery of a pharmaceutical, comprising a first water-erodable adhesive layer and a second, water-erodable non-adhesive backing layer, wherein said pharmaceutical or combination of pharmaceuticals is incorporated with said first adhesive layer, or said second non-adhesive backing layer, or both said first adhesive layer and said second non-adhesive backing layer, and wherein said first water-erodable adhesive layer comprises a film-forming polymer and a bioadhesive polymer, and wherein said second water-erodable non-adhesive backing layer comprises a film-forming polymer, said layered flexible film having a total thickness of from 0.1 mm to 1 mm.